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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/766,528	01/29/2004	Karl Salzwedel	1900.0430002/LBB/SJE	2237

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STERNE, KESSLER, GOLDSTEIN & FOX PLLC
1100 NEW YORK AVENUE, N.W.
WASHINGTON, DC 20005

EXAMINER	
HUMPHREY, LOUISE WANG ZHIYING	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 07/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/766,528	SALZWEDEL ET AL.	
	Examiner	Art Unit	
	Louise Humphrey, Ph.D.	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 August 2004*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-81* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-81* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is in response to the preliminary amendment filed on 19 August 2004. Claims 1-81 are pending.

It is noted that claims 31 and 32 recite the limitation "said detecting" in the third line. There is insufficient antecedent basis for this limitation in the claim.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. §121:

I. Claims 1-16, drawn to a method of treating HIV-1 infection in a patient by administering a compound, classified in class 424, subclass 9.2.

II. Claims 17-22, drawn to a method of treating human blood products comprising contacting a compound with blood products, classified in class 435, subclass 4.

III. Claims 23-41, drawn to a method for identifying compounds that inhibit HIV-1 replication in cells of an animal, classified in class 435, subclass 7.21.

IV. Claims 42-55 and 57-60, drawn to an isolated polynucleotide, a vector comprising the polynucleotide, a host cell comprising the vector, and a virus comprising the isolated polynucleotide, classified in class 424, subclass 205.1.

V. Claims 61-66, drawn to a polypeptide, classified in class 530, subclass 826.

VI. Claims 67-70, drawn to an antibody that selectively binds a mutational sequence in an HIV CA-SP1 protein, classified in class 424, subclass 130.1.

VII. Claim 71, drawn to an antibody that selectively binds SP1 but not CA-SP1, classified in class 424, subclass 130.1.

VIII. Claim 72, drawn to an antibody that selectively binds CA but not CA-SP1, classified in class 424, subclass 130.1.

IX. Claim 73, drawn to an antibody that selectively binds at or near the CA-SP1 cleavage site, classified in class 424, subclass 130.1.

X. Claims 74 and 75, drawn to a compound that is not a dimerthylsuccinyl betulinic acid or dimethylsuccinyl betulin derivative, and a pharmaceutical composition comprising one or more compounds, classified in class 424, subclass 9.1.

XI. Claims 76-80, drawn to a pharmaceutical composition comprising a compound that inhibits HIV-1 replication in cells of an animal and further comprising an anti-viral agent, classified in class 424, subclass 9.1.

XII. Claim 81, drawn to a method of determining if an individual is infected with HIV-1 that is susceptible to treatment by a compound that inhibits p25 processing, classified in class 435, subclass 4.

XIII. Claim 56, drawn to a method of producing a polypeptide, classified in class 435, subclass 70.1.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-III, XII and XIII are unrelated processes. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions operate in different environments (in a patient, in human blood products, and *in vitro*), with different objectives involving different biological mechanisms, different method steps utilizing different equipment or apparatus, and achieve different results.

Inventions IV-XI are unrelated products. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions of polynucleotide, peptides, antibodies and chemical compounds do not share structures, biochemical properties, or functions. Even though Inventions VI-IX are all antibodies, they have different amino acid sequences, binding targets and specificities. Thus, each Invention is patentably distinct and different.

Inventions (X, XI) and (I, II) are related as products and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the products can be used for diagnostic purposes instead of the instantly claimed treatment purposes.

Inventions IV and XIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the polypeptide can be chemically synthesized instead of the claimed host cell expression.

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Restriction to Single Sequence Election

Claims 47-53 specifically claim multiple amino acid and polynucleotide sequences, which are structurally distinct chemical compounds and are not related to one another. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. §121. Each such amino acid sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. §121 and 37 CFR 1.141 *et seq* (See MPEP §803.04). Each sequence is not considered to be a proper member of a Markush group. See M.P.E.P. § 803.02. *In re Harnish*, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and *Ex parte Hozumi*, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, unity of invention exists where compounds included within a Markush group (1) share a common utility, and (2) share a substantial structural feature disclosed as being

essential to that utility. As such, sequences in each of claims 47-53 are not considered to constitute a proper genus/Markush, and are therefore subject to additional restriction.

Furthermore, a search of more than one (1) of the sequences present in these claims presents an undue burden on the Patent and Trademark Office due to the complex nature of the search in terms of computer time needed to perform the search and the subsequent analysis of the search results by the examiner. In view of the foregoing, one (1) sequence is considered to be a reasonable number of sequences for examination.

Accordingly, if Group IV is elected, applicants must further elect a single polynucleotide sequence from SEQ ID NO:4 to 10.

Note that this is not a species election and is separate from group election.

Species Election

This application contains claims directed to multiple patentably distinct species. Should Applicants elect Group III, Applicants are further required to elect:

(A) one labeled substance species from:

(a) labeled antibody specific for CA-SP1 (claim 26); or

(b) labeled 3-O-(3',3'-dimehtylsuccinyl)betulinic acid (claim 27); and

(B) one detection method species from:

(c) measuring the transfer of fluorescent energy (claim 32);

(d) measuring the signal from the fluorescent moiety (claim 31); or

(e) measuring the amount of a labeled antibody bound to SP1 or p24 (claim 33);

(C) one analysis technique from:

(f) western blot (claim 38);

(g) gel electrophoresis (claim 39);

These species are distinct because their structures or procedures are different; thus, each represents a patentably distinct subject matter. Furthermore, the examination of these species would require different searches in the scientific literature, which would not be coextensive. As such, it would be burdensome to search these species together.

Applicant is required under 35 U.S.C. §121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 23 is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. §103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Contact Information

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louise Humphrey, Ph.D. whose telephone number is 571-272-5543. The examiner can normally be reached on Mon-Fri, 9:30 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Louise Humphrey, Ph.D.
10 July 2006

Jeffrey Parkin, Ph.D.
Primary Examiner